UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

VICTORIA BEA GOLDYCH, individually and as surviving wife and as administratrix of the estate of JOHN J. GOLDYCH, JR., deceased,

Plaintiff,

v.

ELI LILLY and COMPANY,

Defendant.

APPEARANCES: **OF COUNSEL:**

FOR THE PLAINTIFF:

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FOR THE DEFENDANT:

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Gary L. Sharpe
U.S. District Judge

MEMORANDUM-DECISION AND ORDER

I. Introduction

Eli Lilly and Company manufactures the prescription drug, Prozac. Alleging that Eli Lilly negligently failed to warn the public about Prozac's risk of suicidal ideation, Victoria Bea Goldych sued when her husband committed suicide after ingesting a generic equivalent manufactured by a non-party. Pending are Eli Lilly's motions to dismiss and for partial summary judgment.[1] *See Dkt. Nos. 31, 32.* For the reasons that follow, the motions are granted and the case is dismissed.

II. Background

In 2004, Goldych filed a state court complaint asserting seven causes of action: *Count I*- Negligence and/or Recklessness; *Count II*- Fraud; *Count III*- Fraudulent Concealment; *Count IV*- Negligent Misrepresentation; *Count V*- Deceptive Business Acts and Practices in Violation of Sections 349 and 350 of New York's General Business Law; *Count VI*- Loss of Consortium; and *Count VII*- Wrongful Death. Eli Lilly subsequently removed pursuant to 28 U.S.C. § 1441. *See Dkt. No. 1.*

Eli Lilly then filed a motion for partial summary judgment on

[1]Eli Lilly's motion for partial summary judgment seeks judgment as a matter of law on Goldych's first cause of action. *See Dkt. No. 31.* Its motion to dismiss seeks dismissal of the remaining causes of action. *See Dkt. No. 32.*

Goldych's first cause of action and a motion to dismiss as to the remaining counts. *See Dkt. Nos. 31, 32.* After oral argument, the court reserved decision. *See Dkt. No. 59.*

III. Facts

Decedent John J. Goldych was under the care of a psychiatrist who prescribed the use of "Prozac." *See Pl. Am. Compl. ¶ 8, Dkt. No. 28.* Pursuant to his psychiatrist's advice, Goldych filled the prescription on several occasions. *See id.*; *see also Eli Lilly SMF ¶ 1, Dkt. No. 31.* Although Prozac was prescribed, the pharmacy employed accepted standards and substituted the generic brand, fluoxetine, which was not manufactured by Eli Lilly.[2] *See Eli Lilly SMF ¶¶ 1-2, Dkt. No. 31.* Goldych never ingested Eli Lilly's product, but the substitute was identical to Prozac. *See Pl. Am. Compl. ¶ 8, Dkt. No. 28*; *see also Eli Lilly SMF ¶ 3, Dkt. No. 31.* Goldych had no history of suicidal ideation or acts before the Prozac prescription or his ingestion of the generic substitute, fluoxetine. *See Pl. Am. Compl. ¶ 65, Dkt. No. 28.*

On September 28, 2003, without warning, Goldych committed suicide

[2]Decedent filled prescriptions for fluoxetine on August 16, 2001, September 22, 2001, November 5, 2001, December 31, 2001, February 26, 2002, July 11, 2003, August 9, 2003, and September 3, 2003. *Eli Lilly SMF ¶ 1, Dkt. No. 31.*

by shooting himself in the head with a shotgun. *See Pl. Am. Compl. ¶ 65, Dkt. No. 28.* A subsequent autopsy disclosed the presence of fluoxetine and bupropion (Wellbutrin SR) in his body. *See Pl. Am. Compl. ¶ 72, Dkt. No. 28.* Prior to Goldych's suicide, Eli Lilly had not warned the public about Prozac's suicidal risks. *See Pl. Am. Compl. ¶ 98, Dkt. No. 28.* However, since Goldych's suicide, the FDA has published two public health advisories and a black box warning noting that patients on Prozac should be alert for suicidal tendencies. *See Pl. Am. Compl. ¶ 99, Dkt. No. 28.*

IV. Discussion

A. Standard of Review

1. Motion to Dismiss Standard

Rule 12(b)(6) provides that a cause of action shall be dismissed if a complaint fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). In other words, the court should dismiss the complaint pursuant to Rule 12(b)(6) if "it appears beyond doubt that the plaintiff can prove no set of facts in support of the complaint which would entitle him to relief." *Twombly v. Bell Atl. Corp.*, 425 F.3d 99, 106 (2d Cir. 2005) (internal quotation marks and citation omitted). "A court's task in ruling on a Rule 12(b)(6) motion is merely to assess the legal feasibility of the complaint, not

to assay the weight of the evidence which might be offered in support thereof." *AmBase Corp. v. City Investing Co. Liquidating Trust*, 326 F.3d 63, 72 (2d Cir. 2003) (internal quotation marks and citation omitted). Therefore, in reviewing a motion to dismiss, a court "must accept the facts alleged in the complaint as true and construe all reasonable inferences in [the plaintiff's] favor." *Fowlkes v. Adamec*, 432 F.3d 90, 95 (2d Cir. 2005) (citation omitted).

2. Motion for Summary Judgment Standard

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986) (citing FED. R. CIV. P. 56(c)); *Globecon Group, LLC v. Hartford Fire Ins. Co.*, 434 F.3d 165,170 (2d Cir. 2006) (citation omitted). All reasonable inferences must be drawn in favor of the nonmoving party. *See Allen v. Coughlin,* 64 F.3d 77, 79 (2d Cir.1995). The moving party "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and

admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (citation omitted); *see also SEC. v. Kern*, 425 F.3d 143, 147 (2d Cir. 2005). "A 'genuine' dispute over a material fact only arises if the evidence would allow a reasonable jury to return a verdict for the nonmoving party." *Dister v. Cont'l Group*, *Inc.*, 859 F.2d 1108, 1114 (2d Cir. 1988) (citation omitted). However, "[c]onclusory allegations, conjecture and speculation...are insufficient to create a genuine issue of fact." *Kerzer v. Kingly Mfg.*, 156 F.3d 396, 400 (2d Cir. 1998).

B. Eli Lilly's Motions

The central issue is whether a prescription drug manufacturer can be liable for death caused by another company's generic equivalent. In its motion to dismiss, Eli Lilly contends that Goldych's claims for fraud, fraudulent concealment, and negligent misrepresentation fail because New York law does not allow recovery for injuries caused by defective products under these theories. Eli Lilly argues that by bringing these claims, Goldych is "masking" claims more appropriately pled under products liability law in order to avoid pleading the elements of a products liability

action.[3]

In its separate motion for partial summary judgment,[4] Eli Lilly argues that Goldych's First Count for negligence and/or recklessness should be dismissed because she cannot prove that the decedent was injured by an Eli Lilly product. More specifically, Eli Lilly maintains that Goldych cannot prove the basic elements of a negligence claim,[5] *i.e.*, that it owed a duty to

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[3]Under settled New York law, "the plaintiff in a products liability case bears the burden of establishing that a defect in the product was a substantial factor in causing the injury." *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 252 (E.D.N.Y. 1999) (internal quotation marks and citation omitted). "New York courts have held that a 'defectively designed' product is one which at the time it leaves the [manufacturer]'s hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use." *Hinkley v. Safepro, Inc.*, 853 F. Supp. 594, 596 (N.D.N.Y. 1994). "[T]he plaintiff must show that the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff's injury." *Arnold v. Krause, Inc.*, 232 F.R.D. 58, 72 (W.D.N.Y. 2004) (internal quotation marks and citation omitted). Further, the manufacturer's breach of its duty to exercise reasonable care must be the proximate cause of the plaintiff's injuries. *See id.* The elements of a products liability claim naturally assume that the defendant manufacturer actually manufactured the product. Additionally, "[i]n a design defect case, there is almost no difference between a *prima facie* case in negligence and one in strict liability." *Bah v. Nordson Corp.*, 00-CV-9060, 2005 U.S. Dist. LEXIS 15683, at *37-38 (S.D.N.Y. Aug. 1, 2005) (internal quotation marks and citation omitted).

[4]In their brief 7.1 statement of material facts, the parties agree on the following three facts: (1) decedent filled prescriptions for fluoxetine on several occasions during 2001, 2002, and 2003; (2) decedent's prescriptions for fluoxetine were filled with generic fluoxetine that was not manufactured by Eli Lilly; and (3) decedent did not ingest fluoxetine manufactured by Eli Lilly. *See Eli Lilly SMF ¶¶ 1-3, Dkt. No. 31.* Eli Lilly maintains that on these undisputed facts, it is entitled to judgment as a matter of law because Goldych cannot prove the essential elements of a negligence action.

[5]Generally, New York law requires that a plaintiff in a negligence action establish: "(1) a duty owed by the defendant to the plaintiff, (2) a breach thereof, and (3) injury proximately resulting therefrom." *Walker v. United States*, 95-CV-6567, 1998 U.S. Dist. LEXIS 8380, at *3 (S.D.N.Y. June 8, 1998) (citing *Solomon v. City of New York*, 66 N.Y.2d 1026, 1027 (1985)).

"In New York, the existence of a duty is a legal, policy-laden declaration reserved for judges." *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 206 (E.D.N.Y. 2004)

Goldych or that it was the cause-in-fact and proximate cause of her damages.

While Eli Lilly brings two separate motions, they present the same legal issue. The court must consider whether a plaintiff can assert claims for negligence, negligent misrepresentation, fraud, and fraudulent concealment against a manufacturer of a product when its product was not the cause of that plaintiff's injuries.[6]

As this question is novel in New York, the court considers recent decisions in other jurisdictions to assist in predicting how the New York Court of Appeals would resolve this issue. The Fourth Circuit Court of Appeals and a district court in the Eastern District of Pennsylvania have recently addressed this precise issue, and the court looks to both decisions for guidance. In *Foster v. Am. Home Products Corp.*, 29 F.3d 165, 166

(internal quotation marks and citation omitted). In proving the duty element,

> [t]he plaintiff must establish not only that a defendant owed a general duty of care to society as a whole, but also that the defendant owed a specific duty running to the particular plaintiff.... In order to determine the existence of a duty in New York, the court should consider and balance the following five factors: (1) the reasonable expectations of the parties and society generally; (2) the proliferation of claims; (3) the likelihood of unlimited or insurer-like liability; (4) disproportionate risk and reparation allocation; and (5) public policies affecting the expansion or limitation of new channels of liability.

Id. (internal quotation marks and citations omitted).

[6]In both motions, Eli Lilly correctly maintains that if the other claims fail, as a matter of law, Goldych's derivative claims for loss of consortium and wrongful death also fail.

(4th Cir. 1994), and *Colaccio v. Apotex*, 05-CV-5500, - - - F. Supp. 2d - - -, 2006 WL 1443357, at *2 (E.D. Pa. May 25, 2006), respectively, both plaintiffs sued a brand name prescription drug manufacturer for deaths caused by another company's generic equivalent.

The defendant in *Foster*, Wyeth, manufactured the brand name prescription drug, Phenergan. *See Foster*, 29 F.3d at 167. A licensed physician prescribed Phenergan for infant twins, Brandy and Bradley Foster, to treat their colic. *See id.* When filling the prescription, the pharmacy substituted the generic form of Phenargan, promethazine, which was manufactured and sold by My-K Laboratories, Inc. *See id.* Promethazine was the bioequivalent of Phenargan. *See id.* After several doses of promethazine, six-week-old Brandy Foster was found dead in her crib. *See id.* Brandy Foster's death was attributed to her ingestion of promethazine. *See id.* Brandy Foster's parents sued Wyeth, the Phenergan manufacturer, for the injuries caused by My-K's generic version, promethazine.

After dismissing the Fosters' claims for negligence, strict liability, and breach of warranty, the district court allowed them to proceed with a claim for negligent misrepresentation. *See id.* Holding that "the allegations of

negligent misrepresentation are an effort to recover the injuries caused by a product without meeting the requirements the law imposes in products liability actions[,]" the Fourth Circuit Court of Appeals reversed the district court's decision. *Id.* at 168. The Fourth Circuit found that a plaintiff seeking recovery for injuries caused by a product must demonstrate that the defendant manufactured the product at issue. *See id*. Because it was impossible to prove that Wyeth manufactured the generic drug, the Circuit dismissed the negligent misrepresentation claim. *See id*.

The district court in *Colaccio* confronted a factual landscape indistinguishable from that faced by this court. *See Colaccio*, 2006 WL 1443357, at *2. The plaintiff in *Colaccio* sued GlaxoSmithKline after his wife ingested a generic version of its antidepressant drug, Paxil, and thereafter committed suicide.[7] *See id*. The plaintiff asserted claims based on a failure-to-warn theory, reasoning that the warnings, which were published by GlaxoSmithKline, were inadequate to inform users of the suicide risks associated with the drug. *See id.* The labeling was prepared solely by the brand name manufacturer, GlaxoSmithKline, and adopted

[7]Unlike Goldych, Colaccio also sued the generic drug manufacturer, Apotex. *See Colaccio v. Apotex*, 05-CV-5500, 2006 WL 1443357, at *2 (E.D. Pa. May 25, 2006).

verbatim by Apotex, the generic manufacturer. *See id*.

Here, the decedent ingested fluoxetine, the generic form of Prozac, and took his own life. Fluoxetine is manufactured by Teva Pharmaceuticals, an Israeli company. In each of her seven alleged theories, Goldych seeks to assign liability to Eli Lilly for a defective product that it did not make or manufacture.

Foster and *Colaccio* provide in-depth analyses in support of their refusal to extend liability to brand name manufacturers, and the court turns to that rationale.

1. *Foster*

In *Foster*, the Fourth Circuit cited policy reasons as support for its refusal to extend liability to a brand name manufacturer for injuries caused by a generic manufacturer's product. Generic manufacturers are not required to perform safety and effectiveness studies on drugs that are the bioequivalent[8] of another FDA approved drug. *See Foster*, 29 F.3d at 169. However, this does not prevent generic drug manufacturers from altering a

[8]"Bioequivalence exists when there is no significant difference between the rate and extent of absorption of two drugs with the same active ingredients administered at the same molar dose under similar experimental conditions, or when a difference in the extent of absorption in such circumstances is not medically significant and certain other requirements are met." *Foster*, 29 F.3d at 169 n.3 (*citing* 21 U.S.C.A. § 355(j)(7)(B) (West Supp. 1994)).

drug's labeling "[t]o add or strengthen a contraindication, warning, precaution or adverse reaction or to delete false, misleading or unsupported indications for use or claims for effectiveness without prior FDA approval." *Id*.

The Fourth Circuit explained that "for economic reasons, generic manufacturers accept without question the studies performed by name brand manufacturers and simply copy verbatim the name brand drugs' package circulars." *Id.* Although generic manufacturers do not actively advertise, they still generate sales when pharmacists substitute generic drugs for name brand prescriptions to cut costs for the customer. For this reason, a "generic manufacturer [can be held] responsible for negligent misrepresentations on its product labels if it did not initially formulate the warnings and representations itself.... [A] manufacturer of generic products is responsible for the accuracy of labels placed on its products." *Id.*

When a generic manufacturer blindly accepts the brand name manufacturer's warnings and representations, it does so at its own risk. *See id.* "In cases involving products alleged to be defective due to inadequate warnings, 'the manufacturer is held to the knowledge and skill of an expert....The manufacturer's status as expert means that at a

minimum he must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby.'" *Id.* at 169-170 (citing *Owens-Illinois v. Zenobia*, 601 A.2d 633, 639 (Md. 1992)). Likewise, as an expert, a generic manufacturer is responsible for the accuracy of labels placed on its products. *See id.*

Goldych's claims for negligence, fraud, fraudulent concealment, and negligent misrepresentation assume that Eli Lilly owed her a duty under New York law. Like the plaintiffs in *Foster*, Goldych maintains that Eli Lilly owed her a duty because it was foreseeable that misrepresentations regarding Prozac could result in personal injury to users of Prozac's generic bioequivalents.

Foster held that "to impose a duty...would be to stretch the concept of foreseeability too far." *Id.* at 171. In alleging a claim for negligent misrepresentation under New York law, "a plaintiff must establish reliance upon a false statement or material misrepresentation or omission[,] [and]...the alleged misrepresentation must have been made by the defendant to the plaintiff." *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 447 (W.D.N.Y. 2001). Moreover, "claims of fraudulent concealment and negligent misrepresentation also require the plaintiff to demonstrate

the existence of a special relationship of trust or confidence between the parties giving rise to a duty to impart correct information[.]" *Rose v. Am. Tobacco Co.*, No. 101996/2002, 2004 WL 986239, at *5 (N.Y. Sup. Ct. Feb. 20, 2004). A duty arises when there is "such a relation that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care." *Foster*, 29 F.3d at 171. In *Foster*, the court found that no such relationship existed between the parties because the plaintiff was injured by a product that the defendant did not manufacture. *See id.* Similarly, Goldych was injured by a product that Eli Lilly did not manufacture.

2. *Colaccio*

In *Colaccio*, the district court premised its holding on the conclusion that the plaintiff's failure to warn claims were impliedly preempted by FDA regulations. *See Colaccio*, 2006 WL 1443357, at *2. To the extent that *Colaccio* contains discussion and analysis of FDA preemption, the court does not rest its decision on this basis since it has not been briefed by the parties.[9] *See id*.

[9]Eli Lilly concedes that at this late stage it "is not attempting to insert a preemption argument into its pending motions." *Eli Lilly Ltr. Brief, Dkt. No. 66.* For a detailed discussion of the federal regulatory process and the intersection between FDA regulations and generic drug manufacturer tort liability, *see Colaccio v. Apotex*, 05-CV-5500, - - - F. Supp. 2d - - -, 2006 WL

The latter part of the *Colaccio* decision examines the duty of care that brand name manufacturers owe to consumers of generic manufacturers' products. Relying heavily on *Foster*, *Colaccio* succinctly states that "all products liability actions *require* proof that the defendant made the product to which the alleged injuries are attributable."[10] *Id*. at *20.

Moreover, in discussing the persuasive weight given to *Foster* by other courts, *Colaccio* recognized that it was not bound by *Foster*. *See id*. at *21. Nevertheless, it noted that "a review of case law reveals that every state and federal district court which has confronted the issue of innovator drug-manufacturer liability has either adopted the *Foster* reasoning or cited *Foster* with approval." *Id*. at *20 (citing *Block v. Wyeth, Inc.*, 02-CV-1077, 2003 WL 203067, at *2 (N.D. Tex. Jan. 28, 2003); *DaCosta v. Novartis AG*, 01-CV-800, 2002 WL 31957424, at *9 (D. Or. Mar. 1, 2002); *Christian v. 3M*, 126 F. Supp. 2d 951, 958 (D. Md. 2001); *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 836 (D. Md. 2000); *Sharp v. Leichus*, 04-CA-

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1443357, at *4-18 (E.D. Pa. May 25, 2006).

[10]Notably, the medication at issue in *Colaccio* was prescribed in New York and the decedent filled the prescription and ingested the medication in New York. *See id.* at *3 n.5. By joint stipulation, the parties agreed that "the law of New York and the law of Pennsylvania are not in conflict, and thus, the laws of Pennsylvania should be applied..." to Counts I through IX. *Id*. The third count asserts a violation of New York Consumer Protection Law, to which New York law governs. *See id.* at *3.

643, 2006 WL 515532, at *4 (Fla. Cir. Ct. Feb. 17, 2006); *Kelly v. Wyeth*, 03-CV-3314, 2005 WL 4056740, at *2 (Super. Ct. Mass. May 6, 2005); *Beutella v. A.H. Robins Co., Inc.*, 05-CV-2372, 2001 WL 35669202, at *2 (Utah Dist. Ct. Dec. 10, 2001)).

Colaccio notes that Pennsylvania and Maryland law differ slightly regarding duty of care and the treatment of certain product liability theories. *See id*. at *21. Nevertheless, *Colaccio* focuses on the causal relationship between the defendant's product and the plaintiff's injury, an essential element governing products liability law in Pennsylvania and Maryland, s*ee id.*, as is also the case in New York.

Colaccio rejects the argument that public policy supports plaintiffs' claims. *See id.* In contrast, it explains that courts "have recognized the societal importance of new and effective prescription drugs...[and] the need not to unduly burden the pharmaceutical industry with unfettered liability." *Id.* (citation omitted). Moreover, *Colaccio* reasons:

> ...the fact that Congress created the FDA in the first place, [coupled with] the statutory scheme embodied in the FDCA, demonstrates that it believes the public interest is best served by the FDA's weighing of the risks and benefits of a particular prescription drug.

Id. Confident in its holding that a brand name manufacturer owes no duty

of care to a plaintiff injured by another company's generic bioequivalent of its drug, *Colaccio* concludes that "even if th[e] [c]ourt's conclusion regarding preemption were found to be improper, the claims against [the brand name manufacturer] must still be dismissed." *Id*. at *22.

3. *Goldych*

As the court has already observed, it must anticipate what the New York Court of Appeals would hold if it were faced with the nuances of this legal conundrum. New York law, like that of Maryland and Pennsylvania, requires a plaintiff seeking recovery for an injury caused by a defective product to prove that the defendant manufactured the product. *See Hinkley v. Safepro, Inc.*, 853 F. Supp. 594, 596 (N.D.N.Y. 1994) (holding that the *manufacturer* must ensure that the product is reasonably safe for its intended use). Goldych concedes that the decedent ingested fluoxetine, a generic substitute for Eli Lilly's drug, Prozac. In an effort to circumvent the requirements of product liability law, Goldych relies on other legal theories which find no support in the law.[11] She has failed to cite any case

[11] "The elements of viable claims of affirmative fraud, fraudulent concealment, and negligent misrepresentation are similar." *Rose*, 2004 WL 986239, at *2. "The elements of a cause of action for...fraud include: (1) representation of a material fact; (2) falsity; (3) scienter; (4) reasonable reliance; and (5) damages." *Neri v. R.J. Reynolds Tobacco Co.*, 98-CV-371, 2000 U.S. Dist. LEXIS 22223, at *17 (N.D.N.Y. Sept. 28, 2000). "Where...the alleged fraudulent acts are the same acts underlying the negligence and strict products liability causes

directly holding that one manufacturer can be held liable for injuries stemming from another manufacturer's product.[12]

Additionally, a New York plaintiff, such as Goldych, seeking recovery for negligence or negligent misrepresentation must demonstrate that the defendant owed her a duty of care. *See Fagan*, 356 F. Supp. 2d at 206. Since Eli Lilly has no duty to the users of other manufacturers' products, Goldych's claims for negligence, fraud, fraudulent concealment, and negligent misrepresentation cannot be maintained on the facts of this case.

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of action, *there is no distinct cause of action for fraud*." *Cottonaro v. Southtowns Indus., Inc.*, 213 A.D.2d 993, 994 (4th Dept. 1995) (emphasis added). In this case, a fraud cause of action is "merely another aspect of the negligence and strict liability causes of action." *Id.* (internal quotation marks and citation omitted).

[12]Goldych cites *Standish-Parkin v. Lorillard Tobacco Co.* to support the proposition that claims for fraud, fraudulent concealment, and negligent misrepresentation can be maintained against manufacturers who never manufactured or sold the defective product used by the plaintiff. *See Standish-Parkin v. Lorillard Tobacco Company*, 12 A.D.3d 301 (1st Dept. 2004). In *Standish*, the estate of a deceased smoker brought a wrongful death claim against a number of cigarette manufacturers. *See id.* at 302. While the plaintiff in that case never smoked cigarettes manufactured by three of the named defendants, the Appellate Division allowed claims of fraud, fraudulent concealment, and negligent misrepresentation to survive against the non-manufacturing defendants' motion for summary judgment. *See id.* at 303. However, the *Standish* case is distinguishable from the instant case. The plaintiff in *Standish* brought suit against a group of cigarette manufacturers. She alleged that the defendants acted in concert with one another to commit a tortious act. In particular, the *Standish* plaintiff alleged that the defendants, as part of the cigarette industry, made false representations to the public about the addictive nature of cigarettes. *See id.* Here, Goldych seeks to hold one pharmaceutical company liable for an allegedly defective product manufactured by another company. Goldych does not claim that Teva Pharmaceuticals and Eli Lilly joined in an agreement or common scheme to make false representations to the public about the drug Prozac and its bioequivalents. The court is unpersuaded by this argument because *Standish* does not open the door for plaintiffs to hold one manufacturer liable for injuries stemming from another manufacturer's product.

The court adopts the rationale articulated in *Foster* and *Colaccio*, and holds that a brand name manufacturer cannot be held liable to a plaintiff allegedly injured by another company's generic bioequivalent. Accordingly, Goldych's first, second, third, and fourth causes of action are dismissed.

C. Violation of General Business Law Sections 349 and 350

New York General Business Law §§ 349 and 350 prohibit "deceptive acts or practices in the conduct of *any* business, trade or commerce or in the furnishing of any service in this state[.]..." N.Y. GEN. BUS. LAW § 349(a); *see also Ortho Pharmaceutical Corp. v. Cosprophar, Inc.*, 828 F. Supp. 1114, 1128-1129 (S.D.N.Y. 1993). "These statutes on their face apply to virtually all economic activity, and their application has been correspondingly broad." *Karlin v. IVF Am., Inc., et. al.*, 93 N.Y.2d 282, 290 (1999). "The reach of these statutes provide[s] needed authority to cope with the numerous, ever-changing types of false and deceptive business practices which plague consumers in our State." *Id.* at 291 (alteration in original) (quotation marks and citation omitted). When these sections of the New York General Business Law were first enacted in 1970, only the Attorney General was empowered to enforce them. *See id.* In 1980, the statute was amended to allow a private right of action. *See id.* Plaintiffs

suing under these sections are entitled to compensatory damages, limited punitive damages and attorney's fees. *See* N.Y. GEN. BUS. LAW § 349(h).

Courts have established the elements of a claim for deceptive practices under § 349, as well as the elements of a claim for deceptive advertising under § 350. The elements for both of these causes of action are (i) that defendants engaged in conduct that was misleading in a material respect; (ii) the deceptive conduct was 'consumer oriented'; and (iii) that the plaintiff was injured '*by reason of*' defendant's conduct. *See Ortho Pharmaceutical Corp.*, 828 F. Supp. at 1128-1129. "A material misrepresentation is made when a statement 'is likely to mislead a reasonable consumer acting reasonably under the circumstances.'" *Anunziatta v. Orkin Exterminating Co., Inc.*, 180 F. Supp. 2d 353, 361 (N.D.N.Y. 2001) (citing *Stutman v. Chemical Bank*, 95 N.Y.2d 24, 30 (2000)). "The test is an objective one....[w]hether a representation is material and whether it is likely to mislead a reasonable consumer may be determined as a matter of law." *Id.*

"To satisfy the 'by reason of' requirement, plaintiff[] need[s] only allege that the defendant['s] material deceptive act[s] caused the injury." *In re: Methyl Tertiary Butyl Ether Prods. Liability Lit.*, 175 F. Supp. 2d 593,

631 (S.D.N.Y. 2001) (internal quotation marks and citation omitted). A plaintiff need not rely on the alleged deceptive conduct to assert a claim under section 349. *See id.* A plaintiff seeking recovery under these statutes must show a causal connection between the defendant's conduct and the plaintiff's injury. *See id.*

Although "[t]he typical case under section 349 generally involves claims arising directly out of a commercial transaction between a plaintiff consumer and a defendant seller, neither the text of the statute nor the case law establishes this requirement." *Id.* at 630-631. "The phrase 'commercial transaction' can be found nowhere in the plain language of the statute, and section 349(h) specifically empowers 'any person who has been injured by reason of any violation of this section' to bring an action." *Id*. (citing N.Y. GEN. BUS. LAW § 349(h)). "Indeed, there is no requirement of privity, and victims of indirect injuries are permitted to sue under the Act." *Id.* at 631 (internal quotation marks and citation omitted). Consumer oriented conduct refers to "conduct that has a broad impact on consumers at large." *Id.* at 630.

Eli Lilly argues that the purchase of prescription drugs is not an ordinary consumer transaction and, therefore, Goldych's New York

Business Law claims must fail. It analogizes to New York cases concluding that New York's deceptive practice laws do not apply in federal securities contexts. *See In re Dean Witter Managed Futures Ltd. P'ship Litig.*, 282 A.D.2d 271, 271-272 (1st Dept. 2001). It compares prescription drugs to securities, noting that neither entails an ordinary consumer transaction for two reasons. First, it maintains that there are levels of third-party intervention[13] for individuals purchasing prescription drugs that are not available to purchasers of ordinary products or services in the consumer marketplace. Secondly, both prescription medications and securities are different than consumer products because they are subject to pervasive federal regulation such as those of the Federal Drug Administration. Goldych maintains that there is an important distinction between federal securities and prescription drugs since "securities are purchased as investments, not as goods to be 'consumed' or 'used.'" *Morris v. Gilbert*, 649 F. Supp. 1491, 1497 (E.D.N.Y. 1986).

Eli Lilly cites no cases to support its argument. However, in *Karlin v.*

[13]Thus, unlike ordinary consumer products, a prescription drug purchaser must receive a prescription from his physician who, after examining the patient, determines the best course of treatment. Then, each patient must present a prescription authorized by a licensed physician to a registered pharmacist to obtain prescription products.

IVF America, Inc., et. al., cited by Goldych in opposition, the Court of Appeals held that plaintiffs may pursue their General Business Law §§ 349 and 350 claims against providers of medical services or products. *See Karlin v. IVF Am., Inc.*, 93 N.Y.2d 282, 291 (N.Y. Ct. App. 1999). The Court held that "a blanket exemption for providers of medical services and products is...contrary to the plain language of the statutes...[and to the] legislative history, as supporters of the consumer protection bills recognized that consumers of medical services and products might be particularly vulnerable to unscrupulous business practices."[14] *Id.* at 291. Finally, in an effort to ease concerns that its holding would result in a tidal wave of consumer protection litigation, *Karlin* explained that such a possibility is "avoided by [the] adoption of an objective definition of deceptive acts and practices, whether representations or omissions, limited to those likely to mislead a reasonable consumer acting reasonably under the circumstances." *Id.* at 294.

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[14]*Karlin* explained, "while the question before us is a novel one, General Business Law §§ 349, 350 have long been powerful tools aiding the Attorney General's efforts to combat fraud in the health care and medical services areas. The Attorney General has relied on these provisions to challenge deceptive and fraudulent practices in contexts as diverse as the marketing of AIDS-related products...; baldness treatments...; abortion counseling clinics...; hearing aids...; and the therapeutic benefits of adjustable beds and chairs." *Karlin*, 93 N.Y.2d at 291.

Here, Goldych's theory is essentially as follows: (1) Eli Lilly materially misrepresented the side effects of Prozac to the public when it failed to provide adequate warnings and/or information about its link to suicidal ideation; (2) the material misrepresentations were consumer oriented because *Karlin* recognized medical services and products as ordinary consumer products; and (3) the decedent was injured by Eli Lilly's material misrepresentations because, ignorant of information regarding Prozac's side effects, he took his psychiatrist's prescription to the pharmacist, generically filled it to save money, ingested the drug, and committed suicide.

While comprehensible, Goldych's theory fails to satisfy the third element of a *prima facie* case. Construing the facts as they most favor her, she has not proven that her husband was injured 'by reason of' Eli Lilly's conduct. She has not shown a causal connection between Eli Lilly's alleged misconduct and her husband's death. The fact that Eli Lilly did not manufacture the ingested drug interrupts the causation element required under sections 349 and 350 of New York's General Business Law. *See Stutman*, 95 N.Y.2d at 29. Goldych must assert a tangible harm, not merely a public harm. Because she cannot prove that the decedent was

injured 'by reason of' Eli Lilly's conduct, Goldych's allegations are insufficient to support a claim under Sections 349 and 350 of New York General Business Law, and must be dismissed.

Alternatively, and even if the business law claims survived, the court could not retain jurisdiction since the monetary requirement necessary for diversity jurisdiction is destroyed with the dismissal of Goldych's common law claims. New York General Business Law § 349(j) provides:

> In addition to the right of action granted to the attorney general pursuant to this section, any person who has been injured by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars, if the court finds the defendant willfully or knowingly violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff.

N.Y. GEN. BUS. LAW § 349(j).

The damages available to Goldych under Sections 349 and 350 are limited. Therefore, she cannot satisfy the amount in controversy requirement of 28 U.S.C. § 1332, and the court would remand to state

court.[15] Accordingly, Eli Lilly's motion to dismiss is granted as to Goldych's fifth cause of action.

D. Goldych's Derivative Claims

Eli Lilly argues that Goldych's wrongful death and loss of consortium claims are derivative of her product liability claims, and therefore, they cannot survive. N.Y. E.P.T.L. § 5-4.1(1) (McKinney 2005) reads in relevant part:

> The personal representative, duly appointed in this state or any other jurisdiction, of a decedent who is survived by distributees may maintain an action to recover damages for a wrongful act, neglect or default which caused the decedent's death against a person who would have been liable to the decedent by reason of such wrongful conduct if death had not ensued. Such action must be commenced within two years after the decedent's death....

N.Y. E.P.T.L. § 5-4.1(1).

Because Goldych's claims for wrongful death and loss of consortium are derivative of the other claims asserted in her complaint which the court has now dismissed, the derivative claims are also dismissed.

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[15] 28 U.S.C. § 1332(a)(1) provides:

> The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $ 75,000, exclusive of interest and costs, and is between...[c]itizens of different states.

28 U.S.C. §1332(a)(1).

WHEREFORE, for the foregoing reasons, it is hereby

ORDERED that Eli Lilly's motion to dismiss is **GRANTED**, and it is further

ORDERED that Eli Lilly's motion for summary judgment is **GRANTED**, and it is further

ORDERED that all of Goldych's claims are **DISMISSED**, and it is further

ORDERED that the Clerk provide a copy of this Decision and Order to the parties.

IT IS SO ORDERED.

July 19, 2006
Albany, New York

Gary L. Sharpe
U.S. District Judge